DEPARTMENT OF HEALTH AND HUMAN SERVICES HFI-35

Food and Drug Administration
Baltimore District Office
Central Region
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2307

July 31, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Edward F. Stanfield, President
Edrich Farms, Inc.
2829 Offutt Road
Randallstown, Maryland 21133

Dear Mr. Stanfield:

The Food and Drug Administration (FDA) conducted an inspection of your sprout manufacturing facility located at 2829 Offutt Road, Randallstown, Maryland, on July 6 and 11, 2000. This inspection revealed insanitary conditions in the manufacturing of broccoli sprouts in violation of the Food, Drug and Cosmetic Act (FD&C Act).

Specifically, the sprouts are adulterated within the meaning of Section 402(a)(4) of the FD&C Act in that they are being produced under insanitary conditions that may render the sprouts injurious to health. The conditions under which the sprouts are being produced are considered insanitary, since effective preventative controls, particularly microbial testing of spent irrigation water, have not been implemented by your facility.

This violation is not intended to be an all-inclusive list of violations at your facility. It is your responsibility to ensure compliance with all applicable laws and regulations.

You should take prompt action to correct this deviation. Failure to promptly correct this deviation may result in regulatory action being taken without further notice. This may include seizure and/or injunction. I am enclosing a copy of a recently published FDA guidance document entitled "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production." To address our concerns, you may wish to establish a program as described in the guidance document, or an alternative approach that satisfies the requirements of the FD& Act and the pertinent regulations.

We have received your written response dated July 24, 2000, which contains a commitment to implement a field-testing program. Please notify us in writing within 15 working days of receipt of this letter the details of the field-testing program that you plan to implement.

Your response should be directed to Rosalie Bucey, Compliance Officer, U.S. Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201, telephone number (410) 962-3591, extension 143.

Sincerely,

Lee Bowers
District Director

Enclosure